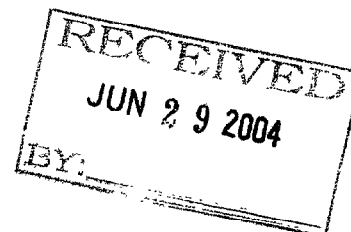




JUN 23 2004

June 16, 2004

Dr. Robert Moore
Division of Compliance and Enforcement/ONPLDS
Center for Food and Safety and Applied Nutrition
U.S. Food and Drug Administration
HFS - 810
5100 Paint Branch Parkway
College Park, MD 20740



Dear Dr. Moore:

Inverness Medical Nutritionals Group has launched a new dietary supplement and wishes to notify the Food and Drug Administration. The supplement, *Hy-Shape (or Hydroxyless)*, consists of the following active ingredients (per 3 capsules): Calcium (as hydroxycitrate) 152 mg; Chromium (as polynicotinate) 133 mcg; Potassium (as chloride and as hydroxycitrate) 225 mg; a Proprietary Blend 1.71 g containing *Garcinia cambogia* (fruit and rind) extract standardized for (-) hydroxycitric acid, *Gymnema Sylvestre* leaf extract standardized for gymnemic acid, Glucomannan (*Amorphophallus konjac*), Alpha lipoic acid, Willow bark extract (purple and white) standardized for salicin, L-Carnitine (as tartrate); a Tea Blend (393 mg) consisting of Green tea leaf extract standardized for 95% polyphenols [70% catechins (45% epigallocatechin gallate -90 mg EGCG)], caffeine (as caffeine anhydrous), and Guarana extract (seed) standardized for 200 mg caffeine, and will bear the following structure/function statements on the label(s).

Display Panel (Bottle Label)

Weight Loss Support Formula

- Supports Weight Loss
- Boosts Energy
- Enhances Metabolism
- Suppresses Appetite

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

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Side Panel (Bottle Label)

It also contains the following warning:

WARNING: Not intended for use by persons under 18. Do not use if you are pregnant or nursing. Consult a physician (medical doctor) before using if you have been treated for or diagnosed with, or have a family history of any medical condition including, but not limited to: high blood pressure, cardiac arrhythmias, heart, kidney, or psychiatric disease, stroke, angina, diabetes, asthma, nervousness, anxiety, depression, seizure disorder, peptic ulcers, or if you are using any prescription or over-the-counter drug, or if you are sensitive to the effects of caffeine. Do not use if you are taking a monoamine oxidase inhibitor (MAOI), selective serotonin reuptake inhibitor (SSRI) or any other dietary supplement, or any other over-the-counter drug containing ephedrine, caffeine, pseudoephedrine, or phenylpropanolamine (ingredients found in certain decongestant, allergy, asthma, cough/cold, and weight control products), herbal or botanical products, aspirin, any anticoagulant (blood thinner) [Taking aspirin or any anticoagulant with this product can lead to or worsen stomach ulcers and can potentially lead to uncontrolled bleeding], or any other ephedrine group alkaloid, or other ingredients that have a known stimulant effect. One serving (3 capsules) of this product contains about as much caffeine as two cups of coffee. Do not combine with other sources of caffeine (i.e. tea, coffee, and cola beverages) Stop use for 2 weeks after 12 weeks of continuous use. Consult a physician before starting any diet or exercise program. Discontinue use and call a physician immediately if you experience: rapid or irregular heartbeat, dizziness, headache, shortness of breath, sleeplessness, tremors, nausea, nervousness, tingling sensations, chest pains, changes in behavior, loss of consciousness or other similar symptoms. Exceeding the recommended serving and/or improper use of this product will not improve results and may cause serious adverse health effects. Do not use with alcohol. Do not use if you have a history of drug use. Do not use during strenuous activity in high-temperature conditions. Use only as directed. Taking this product without adequate fluid may cause it to swell and block your throat or esophagus and may cause choking. Do not take this product if you have difficulty in swallowing. If you experience chest pain, vomiting or difficulty in swallowing or breathing after taking this product, seek immediate medical attention. **KEEP OUT OF THE REACH OF CHILDREN.**

We certify that the information contained in this notice is complete and accurate, and we have substantiation that the above structure/function statements are truthful and not misleading.

Sincerely,



William J. Neumann

Vice President

Quality and Regulatory Affairs